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To the Subcommittee on Commerce, Trade, and Consumer Protection Hearing on "TSCA and Persistent, Bioaccumulative, and Toxic Chemicals: Examining Domestic and International Actions"
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I would very much like to thank the Chairman, Mr. Rush, Ranking Member, Mr. Whitfield and Members of the Subcommittee for inviting me to testify before you today. My name is Christina Cowan-Ellsberry. I have a Ph.D. in Civil Engineering with emphasis in Environmental Engineering. I have worked in the field of environmental and human safety and risk assessments for chemicals for over 30 years. Because I was invited as a technical witness to this hearing on Persistent, Bioaccumulative and Toxic Substances (PBTs) in TSCA, I thought it would be relevant for this committee to understand my background on this topic.

I have worked on the development of the technical criteria and process for identifying and evaluating the safety of PBTs since the 1990s. I was a technical contributor to the Canadian Toxic Substance Management Policy criteria and assessment approach, and to their technical guidance documents on how to determine if a substance under evaluation meets the Persistence, Bioaccumulation and/or Toxicity criteria. I contributed to the technical criteria and process for UN Economic Cooperation for Europe's (UNECE) Persistent Organic Pollutants (POPs) Protocol to the Long-Range Transboundary Air Pollution (LRTAP) Convention and the NAFTA Commission for Environmental Cooperation's Sound Management of Chemicals Initiative both of which contain PBT assessments. I served as a representative to the Criteria Expert Group for the UN's Stockholm Persistent Organic Pollutants Convention. I have also contributed technical comments to the REACH implementation approach for PBTs. On a detailed scientific level, I have organized and been a key contributor in several technical workshops and discussion groups both nationally and internationally on various aspects of the science and approaches to identifying and evaluating PBTs. This included the most recent Society of Environmental Toxicology and Chemistry's Pellston Workshop whose goal was to improve the process of identification and evaluation of chemicals against the PBT criteria. Furthermore, I am the chairperson for the International Life Sciences Institute's Health and Environmental Sciences Institute (HESI) Bioaccumulation Project Committee whose mission is to develop the tools needed for improving the assessment of the potential bioaccumulation of organic substances. In all of these activities, I have worked with staff from the US EPA. You can see from this brief summary of my background that I have both a comprehensive knowledge of the technical basis for the criteria, identification and assessment of Persistent, Bioaccumulative and Toxic (PBT) substances and the subcategory of organic PBTs called Persistent Organic Pollutants (POPs)s. In addition, I understand the goals of the various global PBT programs and how these lead to apparent differences in criteria and consequences.

INTERNATIONAL PROGRAMS HAVE BEEN ADDRESSING PBT'S FOR SEVERAL DECADES. PBT identification and assessment for new and existing chemicals has been a priority of governments including the United States since the early 1990s. The first national regulatory effort to establish criteria and a process to identify PBT substances was Environment

Canada's Toxic Substance Management Policy (TSMP), which was published in 1995[1]. An integral part of this policy was development and publication of the first set of screening criteria for identifying if a substance was persistent and/or bioaccumulative. The objective of the policy and its associated criteria was to provide a framework for making science-based decisions to identify and prioritize PBT substances for risk assessment and potential management. This scientific framework and criteria for Persistence and Bioaccumulation were also incorporated into the NAFTA CEC's Sound Management of Chemical's initiative (implemented in 1995)[2] and the UN ECE's Persistent Organic Pollutants protocol within their Long-Range Transport and Persistence (LRTAP) Convention (Entered into force 2003)[3]. Within the UN ECE POP's protocol, the persistence criteria for water and sediment were reduced slightly from those included in the TSMP. These final set of criteria for Persistence and Bioaccumulation were eventually incorporated into the UN Stockholm Convention on Persistent Organic Pollutants (entered into force 2004)[4]. Initially, in all these conventions, toxicity identification was determined by a risk based assessment called a risk profile but more recently a numeric criterion has also been incorporated in addition to the risk profile. Based on this vetting and discussion there is now international consensus that the UN Stockholm Convention and the Canadian TSMP criteria are scientifically-based and appropriate because these criteria are now incorporated into many national PBT regulatory programs. In Table 1, I illustrate the cross-section of Persistence and Bioaccumulation criteria used in several national and international programs. This table illustrates that although there are some differences in criteria, most regulatory programs have the same or very similar criteria. The differences in criteria typically reflect differences in regulatory objectives.

Using these criteria and assessment processes, very effective PBT screening identification and assessment processes have been on-going in Canada and Europe for approximately a decade. The Canadian Government in the Canadian Environmental Protection Act reauthorization in 1999 initiated a process to identify and prioritize PBT substances that are in commerce in Canada together with chemicals that have concerns for human health. This initial screening or categorization of the approximately 23,000 substances on the Domestic Substances List was completed in September 2006. Environment and Health Canada are now conducting screening assessments on the 200 highest priority substances (of which 77 were identified as potential PBT's) to determine whether the substance truly meets the criteria and if it is "toxic" or capable of becoming "toxic" as defined in CEPA 1999. This determination of toxic consists of conducting a risk assessment, which integrates the known or potential exposure of a substance with known or potential adverse effects on the environment and humans. A similar initiative was undertaken in Europe. Beginning in June 2001, the European Chemicals Bureau conducted a screening study to identify PBT substances among the 2682 high production volume chemicals[5]. They identified an initial list of 127 substances, which was finally reduced to 24 substances by incorporating data from manufacturers as part of a scientific review by regulators from across Europe. The next step in each of these programs after the initial PBT identification is to conduct

[1] http://www.ec.gc.ca/toxics/TSMP/EN/execsum.cfm
[2] http://www.cec.org/Page.asp?PageID=924&SiteNodeID=237
[3] http://www.unece.org/env/lrtap/pops_h1.htm
[4] http://chm.pops.int/
[5] The approach and results are described at http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt

an evaluation of the sources, major emissions pathways to the environment in order to establish the most appropriate and effective measures to minimize risks to humans and the environment.

Since the 1990s, the US EPA has also been actively involved in developing a strategy for identifying PBTs and in assessing these priority substances for more detailed review of their persistence, bioaccumulation and toxicity properties, risk assessment and management within several TSCA programs. On November 4, 1999, EPA issued its final policy statement (64 FR 60194) on a category for PBT new chemicals which represented the first formal statement of national policy regarding new chemical "persistent organic pollutants" ("POPs"). The policy statement provided guidance criteria for persistence, bioaccumulation, and toxicity for new chemicals (Table 1) and advised the industry about EPAs regulatory approach for chemicals meeting the criteria. Using these criteria, the U.S. EPA initially developed a list of 53 chemicals, which was reduced to 28 organic chemicals and 3 metals based on comments and new information during public comment on the methodology. This list is used to help implement EPA's national RCRA waste minimization policy to reduce the generation of PBT chemicals found in RCRA hazardous waste. In 2004, EPA established a goal of a 10 percent reduction of these PBT priority chemicals by 2008 compared to a 2001 baseline. US EPA has complemented this waste minimization policy by adding many of these PBT chemicals to the Toxic Releases Inventory (TRI) reporting. For existing chemicals, PBT screening and the developed list of priority PBT substances has been used as one basis for choosing substances for development of EPA's chemical action plans. These National Action Plans for several of the chemicals included on the Priority Chemical list which include dioxins/furans, hexachlorobenzene, mercury, benzo(a)pyrene, and six additional polycyclic aromatic hydrocarbons (PAHs) are also used as part of the US's international commitments under NAFTA, the Canada-United States Binational Toxics Strategy, the United Nations Environment Programme's Persistent Organic Pollutants (POPs) effort, and the United Nations Economic Commission for Europe's Long Range Transport Air Pollutants (LRTAP) Persistent Organic Pollutants effort.

Since 1999, PBT screening has been an integral part of EPA's New Chemical PMN review under TSCA to avoid approving new PBTs. To provide transparency to stakeholders, EPA developed an evaluation tool called the PBT Profiler, which predicts PBT potential of chemicals. This assessment tool estimates the environmental persistence (P), bioconcentration potential (B), and aquatic toxicity (T) of discrete chemicals based on their molecular structure and compares the results to the PBT criteria The model compares results with the PBT criteria established for Premanufacture Notices (PMNs) submitted under section 5 of TSCA. This tool has been recognized as an extremely valuable contribution to the international community – regulators, industry and scientists - involved in PBT identification and assessments.

TSCA MUST BE FLEXIBLE TO INCORPORATE STATE OF THE SCIENCE. These initiatives in United States, Canada, and Europe have illustrated that it is possible to identify PBT substances and to conduct risk-based assessments; however, the process can be a scientifically challenging and requires the active involvement of manufacturers and scientists. Some of these challenges are related to the low water solubility, difficulty in measurement, and attachment to surfaces of these types of chemicals, which cause them to be classified as "difficult to test" substances. Thus, the scientific community has been working on developing guidance on how to evaluate chemicals with PB and T properties using readily available data. There has also

been an emphasis on developing improved test methods or modifying existing test methods so that the results are valid for "difficult to test" substances. For example, bioaccumulation tests have been modified to include new *in-vitro* metabolism methods. Because of the wide range of challenges and the importance of PBT assessments, many scientific groups are actively involved in research to improve assessment approaches and ensure greater confidence in the final PBT conclusions. For example, the Society of Environmental Toxicology and Chemistry conducted a Pellston Workshop whose goal was to improve the process of identification and evaluation of chemicals against the PBT criteria building on the most recent science[6]. Organization for Economic Co-operation and Development (OECD) and HESI's Bioaccumulation Committee are actively engaged in developing and validating alternative methods for Bioaccumulation assessments. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) has also developed guidance on how to conduct risk assessments for PBT substances[7]. Given the rapid improvement in the test methods and guidance it is critically important for US EPA to contribute to and incorporate the most current science and scientific understanding in their assessments, especially as these relate to reducing animal testing.

One recent example of the effort to improve the process and guidance for PBT identification and assessment was Society of Environmental Toxicology and Chemistry's (SETAC) Pellston Workshop. This workshop which was held in January of 2008 brought together experts from academia, government, and industry to review and discuss significance recent advancements in our understanding of the behavior and potential impact of PBTs in the environment as well as to develop recommendations for policy-makers on how to improve the science in the regulatory context. One concern raised by the workshop participants is that most of current national and international regulations define PBTs in terms of fairly strict pass or fail criteria. This is appropriate for early screening and prioritization but fails to recognize that the state of the science and our understanding of PBT which have vastly improved since these criteria were developed in the late 1970s and early 1980s. The incredible evolution in the state of the science since then has produced new insights into PBT substances and an array of new methods to identify PBT chemicals but the regulatory programs have not kept up with the rapid development in environmental chemistry and toxicology. As a result, scientists sometimes bring forward new data using the state-of-the-science test methods and evaluations, but find the data rejected because the regulatory framework does not allow for its consideration. With this background, any revision of existing frameworks for evaluating PBTs need to provide adequate flexibility to allow the introduction of additional, new, and emerging scientific evidence into the processes. One example is the application of bioconcentration factors to judge whether a substance is Bioaccumulative. Under most of the current regulatory schemes the only options are older models known as the OECD 305 tests which use a large number of fish and are very time consuming and costly. Providing flexibility to incorporate improved predictive models, in vitro metabolism test data, shorter less animal intensive screening BCF test data, and field data in the

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[6] **Integrated Environmental Assessment and Management** Volume 5 Issue 4 Nine papers on p. 535-711.

[7] ECETOC. TR 098 - Risk Assessment of PBT Chemicals. February 2006 http://www.ecetoc.org/index.php?mact=MCSoap,cntnt01,details,0&cntnt01by_category=5&cntnt01template=display_list_v2&cntnt01order_by=Reference%20Desc&cntnt01display_template=display_details_v2&cntnt01document_id=277&cntnt01returnid=89

evaluation would result in improved confidence in the PBT assessments while reducing cost, time and animals used in testing. The modernization of TSCA should be flexible to incorporate new, validated methods that used advanced state-of-the-science methods.

PBT'S MUST BE PRIORITIZED, ASSESSED FOR RISK AND, WHERE APPROPRIATE, MANAGED. For PBT screening identification, the chemical substances are evaluated as to whether they meet any of the three criteria, i.e., are they persistent or bioaccumulative or toxic. Depending on the objective of the particular regulatory framework within which the PBT identification is contained, the substances may be categorized into different groups by level of concern or priority depending on whether the substance meets a combination of these criteria. The highest priority for risk assessment and potential management are those substances that meet all three criteria - the combination of Persistence and Bioaccumulation and Toxicity. Canada's CEPA 1999 law took the focus beyond combined PBT to specify that chemicals which were persistent and toxic only (PiT) or bioaccumulative and toxic only (BiT) should also be prioritized, albeit with the very highest priority placed first on chemicals that meet all three criteria for P, B and T. The EU PBT strategy focused priority on those chemicals that are P, B and T and those that are very persistent and very bioaccumulative only (i.e., meet UN Stockholm Criteria P and B criteria) which are called vPvB. These options in how to prioritize substance for further scrutiny and risk-based assessment have some scientific basis, and can be incorporated into a priority setting approach based on PBT categorization. It is important to recognize that even if the same criteria are used to identify a PBT, the different regulations may designate them by different abbreviations (Table 1).

In all of these PBT identification programs, the initial prioritization of the substance is based on whether it meets the combination of PB and T criteria. The next step is to conduct a scientific risk-based assessment of potential for harm. This risk assessment process is separated from any final risk management decision although it can be used to inform potential risk management options. Furthermore, there is a range of management options available depending on uses of the substance. For example in the Stockholm protocol, management options range from 1) prohibition and legal or administrative action to eliminate the production and use of the chemical (Annex A) to 2) allowing production and specific exemptions for use by specific parties (Annex B). Environment Canada's PBT assessments also allow for range of management options from no-further action at this time to implementation of virtual elimination.

All of these programs, both nationally and internationally have illustrated that the use of PBT identification for existing chemicals would result in a relatively limited number of substances to assess and for which, if necessary, develop management strategies. It is not possible to predict the final number of PBT substances currently in commerce nationally and/or internationally that will require risk assessment and potential management; however, it would appear to be less than 100. For example, within the Stockholm POPs Protocol the initial number of high priority substances was 12 many of which were no longer manufactured. Currently an additional 9 substances have been recommended for listing in Annexes A, B and/or C with specific control measures. An additional three substance are under review. The EU review of their 2683 high volume chemicals resulted in identification of 24 PBT substances. The Canadian DSL categorization of 23,000 substances identified 77 PBT substances. The US EPA list of organic priority PBT substances is 30. There is a significant overlap of the substances across the lists. Some of the differences in numbers relates to the targeted objectives of the different national

programs, the actual value of the criteria and the way that these criteria are combined in the final identification (see Table 1).

RATIFICATION OF INTERNATIONAL CONVENTIONS SO THAT EPA CAN BRING SCIENTIFIC LEADERSHIP TO INTERNATIONAL FORA. My concern is that although the US and EPA scientists have publically committed to working with the international community to address chemicals of international concern and the EPA scientists were very active in the discussions on PBT screening criteria and assessment process on many of these international protocols including UNECE's POPs protocol and the Stockholm POPs convention, the US has not become a signatory to either of these critically important chemical management conventions. In fact, the October 5, 1998 notice that signaled the development of EPA's PBT strategy stated that part of the intent of this notice was to alert the parties involved in negotiation of the United Nations Environment Programme (UNEP) POPs Convention that the US was taking leadership on this issue. It was envisioned that this strategy could serve as a model for other countries in taking steps to discourage the introduction of chemicals with PBT properties as new chemicals and pesticides. In fact, the development of the PBT profiler has been a key contribution to this strategy and a tool that is used internationally as mentioned previously. However, the leadership position of the US in international chemical management has been weakened by not becoming a full signatory to these critically important conventions. I strongly urge the US to become a signatory to these Conventions so that U.S. government scientists can once again bring their knowledge and expertise forward in leadership internationally as full parties to these conventions. Within this role, the US and its scientists can also play an important role in leading first world nations to increase their participation in the global identification, risk-based assessment and management of PBTs which will improve the safety of US citizens from these international pollutants. Because, as mentioned previously, the process of identification, assessment and where necessary, risk management of PBTs is being continuously improved, EPA scientists should be in a position to provide leadership within these technical areas in the US as well as globally. Full US participation in these agreements is critical in maintaining, risk-based and science-based processes in PBT identification, assessment and management efforts globally. Thus, as you consider modernization of TSCA, in addition to becoming full signatories and parties to these conventions, it will be very important to provide adequate funding of EPA scientists to be integral members of national and international groups working on the continual improvement of methods and assessment approaches.

STRONG NATIONAL PBT PROGRAM. It is also important that the US EPA develop a stronger Federal PBT program to build confidence so that States do not have to take separate and potentially conflicting actions to identify and manage these types of substances. Most states don't have the depth of scientific expertise nor the number of staff to effectively conduct these scientifically challenging assessments. Thus, a role that EPA can play is to develop and promulgate methods for identification and assessment and provide assistance to states that are interested in investigating PBTs. To ensure acceptance and a technically strong, comprehensive process for identification and assessment of PBT's, these methods should be developed within a scientific multi-stakeholder process or through the use of a Scientific Advisory Panel. This will also require a commitment from Congress for full funding, staffing, and support of such a strong Federal PBT program.

Ultimately a reform of TSCA that contains a strong commitment and adequate funding to a Federal program for PBT identification, assessment and management and US leadership internationally in PBT conventions will encourage technical innovation of new chemicals and products that will improve the lives of US citizens and the international community. As a result, this modernized TSCA will benefit the US citizens as it will contribute to improving global public health and the environment for existing chemicals and provide assurance that new chemicals that have PBT properties will not enter commerce.

Mr. Chairman and distinguished members of the subcommittee, thank you again for the invitation to testify here today. In the meantime, I look forward to answering any questions you may have.

Table 1: Persistence and Bioaccumulation Criteria and their use in Various Regulations and Conventions.

Bioaccumulation Criteria _____ Persistence Criteria (half-lives)	BCF/BAF* > 1000	BCF/BAF* > 2000	BCF/BAF* > 5000
Water = 180 days Soil = 180 days Sediment = 360 days			• US EPA New Chemicals Program (Ban)[2] • Canada TSMP [3] NAFTA SMOC [6]
Water = 60 days Soil = 180 days Sediment = 180 days		• EU TGD PBT [7]	• Stockholm POPs Protocol [4] • UNECE POPs Protocol [5] • EU vPvB [7]
Water = 60 days Soil = 60 days Sediment = 60 days	• US EPA New Chemicals Program (SNUR)[1]		

*Bioconcentration Factor (BCF)/Bioaccumulation Factor (BAF)

1. US EPA New Chemicals Program. 64 FR 60194 Category for Persistent, Bioaccumulative and Toxic New Chemicals Nov. 4 1999. TSCA 5e Action. Order Pending Testing/Significant New Use Rule (SNUR). Criteria also used in other TSCA regulatory programs.
2. US EPA New Chemicals Program. 64 FR 60194 Category for Persistent, Bioaccumulative and Toxic New Chemicals Nov. 4 1999. TSCA 5e Action. Ban Pending Testing. Criteria also used in other TSCA regulatory programs.
3. Canadian TSMP Criteria. http://www.ec.gc.ca/toxics/TSMP/EN/execsum.cfm . These criteria were used in the Categorization of the DSL.
4. Stockholm Persistent Organic Pollutants Protocol. http://chm.pops.int/ Annex D contains the criteria
5. *1998 Aarhus Protocol on Persistent Organic Pollutants* http://www.unece.org/env/lrtap/pops_h1.htm
6.NAFTA Commission for Environnemental Cooperation's Sound Management of Chemicals Initiative. http://www.cec.org/Storage/44/3631_Crit-2-e_EN.pdf
7. European Commission Joint Research Centre Institute for Health and Consumer Protection. for http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt